



EXPRESS MAIL NO. EV336617742US

**RESPONSE UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE - EXAMINING GROUP 1630**

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

OCT 31 2003

Applicants : Raymond L. Houghton *et al.*
Application No. : 10/076,622
Filed : February 13, 2002
For : COMPOSITIONS AND METHODS FOR THE THERAPY AND
DIAGNOSIS OF BREAST CANCER

TECH CENTER 1600/2900

Examiner : Janet L. Epps-Ford, Ph.D.
Art Unit : 1635
Docket No. : 210121.470C11
Date : October 27, 2003

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AND AMENDMENT UNDER 37 C.F.R. § 1.116

Commissioner for Patents:

In response to the Office Action dated August 25, 2003, please amend the application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 3 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1.-10. (Canceled)

11. (Previously Presented) A method for stimulating an immune response in a patient, comprising administering to the patient a composition comprising a first component selected from the group consisting of physiologically acceptable carriers and immunostimulants, and a second component selected from the group consisting of:

- a) a polypeptide sequence comprising SEQ ID NO:475; and
- b) polypeptides having at least 90% identity to the polypeptide set forth in SEQ ID NO:475, wherein said polypeptides having at least 90% identity are immunologically reactive with an antibody and/or T cell that reacts with the polypeptide set forth in SEQ ID NO:475.

12. (Previously Presented) A method for stimulating an immune response in a patient, comprising administering to the patient a composition comprising a first component selected from the group consisting of physiologically acceptable carriers and immunostimulants, and a second component comprising a polypeptide comprising at least 20 contiguous amino acids of the polypeptide set forth in SEQ ID NO:475, wherein said polypeptide comprising at least 20 contiguous amino acids is immunologically reactive with an antibody and/or T cell that reacts with the polypeptide set forth in SEQ ID NO:475.

13. (Currently Amended) The method of claim 11 or 12 wherein said immunostimulant is selected from the group consisting of monophosphoryl lipid A, 3-de-O-acylated monophosphoryl lipid A, and a saponin, alone or in combination MPL[®], QS21, QS7, Esein, Digitonin, Quil A, and a combination of monophosphoryl lipid A together with an aluminum salt.

REMARKS

Reconsideration of the subject application is respectfully requested in view of the above-noted amendments and the following remarks. Claims 11-13 are currently pending in this application. With the above amendments, claim 13 has been amended. Support for the amendment can be found throughout the specification as filed, for example, at page 99, lines 15-29. No new matter has been added. It should be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Rejections under 35 U.S.C. § 112, first paragraph (Indefiniteness)

Claim 13 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Action contends that claim 13 contains trademark/trade name MPL[®], QS21, Q27, Escin, Digitonin, and Quil A. The Action further contends that the specification as filed does not provide a definitive description of the immunostimulants corresponding to these trademark/trade names.

Without acquiescing to the rejection, Applicants have amended claim 13 to recite the generic terms "monophosphoryl lipid A, 3-de-O-acylated monophosphoryl lipid A and a saponin" and to remove recitation of "MPL[®], QS21, Q27, Escin, Digitonin, and Quil A". Support for the amendment can be found, for example, at page 99, lines 15-29 of the specification. Accordingly, Applicants submit that the rejection has been obviated and respectfully request its withdrawal.

Rejections under 35 U.S.C. § 102(e)

Claims 11-12 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Jager *et al.* (WO 01/47959 A2). In particular, the Action contends that Jager *et al.* teaches the immunotherapeutic treatment of a patient comprising administering the peptides disclosed in the reference or immunoreactive portions thereof. The Action further asserts that the peptides

disclosed in Jager *et al.* include a protein comprising the full-length sequence of SEQ ID NO:475.

Applicants respectfully traverse this rejection on the following grounds. Applicants submit that the cited reference claims priority to two U.S. Patent Applications, 09/451,739, filed November 30, 1999 and 09/602,362, filed October 24, 2000. The sequence of SEQ ID NO:23 of Jager *et al.*, that the Action contends comprises the claimed polypeptide of SEQ ID NO:475, was not disclosed in the priority document 09/451,739, filed November 30, 1999 (see enclosed copy of priority document 09/451,739). As such, SEQ ID NO:23 is only entitled to the later priority date of U.S. Application No. 09/602,362, or October 24, 2000. Accordingly, Applicants submit that the disclosure of SEQ ID NO:23 of Jager *et al.* is not prior art and cannot anticipate the presently claimed subject matter. Applicants respectfully submit that the rejection has been obviated and may be properly withdrawn.

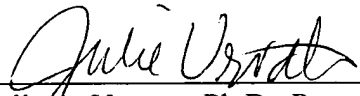
The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants urge that all of the claims remaining in the application are believed to be in condition for allowance. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

Raymond L. Houghton *et al.*

SEED Intellectual Property Law Group PLLC



Julie A. Urvater, Ph.D., Patent Agent
Registration No. 50,461

JAU:tt

Enclosure:

Postcard

Copy of Priority Document 09/451,739

701 Fifth Avenue, Suite 6300
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Phone: (206) 622-4900
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416841_1.DOC



COMBINED DECLARATION AND POWER OF ATTORNEY

Attorney Docket No.
LUD 5615 (09905230)

As a below named inventor, I hereby declare that:

I residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **"ISOLATED NUCLEIC ACID MOLECULES ENCODING CANCER ASSOCIATED ANTIGENS, THE ANTIGENS PER SE, AND USES THEREOF"**, the specification of which

(check one) ☒ is attached hereto.☐ was filed on
and was amended on

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) or § 365(b) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior U.S. or PCT international application in the manner provided by the first paragraph of Title 35, U.S.C. § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the following attorneys to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Peter F. Felfe, Reg. No. 20,297; John E. Lynch, Reg. No. 20,940; Norman D. Hanson, Reg. No. 30,946; John A. Bauer, Reg. No. 32,554; James Zubok, Reg. No. 38,671; Mary Ann Schofield, Reg. No. 36,669; James R. Crawford, Reg. No. 39,155; Robert Gorman, Reg. No. 41,790; Katrine A. Levin 41,941, Reg. No. and Eric Sinn, Reg. No. 40,177 my attorneys with full power of substitution and revocation. Address all telephone calls to NORMAN D. HANSON, Esq., at (212) 318-3000 Address all correspondence to:

FULBRIGHT & JAWORSKI L.L.P., 666 Fifth Avenue, New York, New York 10103

are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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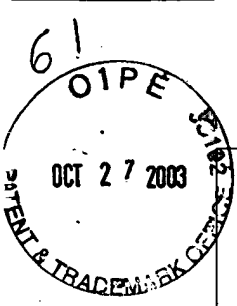
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Full Name of Seventh Investor	Investor's Signature	Date
Residence	Citizenship	
Post Office Address		



Corres. and Mail

10-29-03

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AF/1600

**TRANSMITTAL
FORM**

(To be used for all correspondence
after initial filing)

Application Number	10/076,622
Filing Date	February 13, 2002
First Named Inventor	Raymond L. Houghton
Art Unit	1635
Examiner Name	Janet L. Epps-Ford, Ph.D.
Attorney Docket No.	210121.470C11

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ENCLOSURES (check all that apply)

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☒ Amendment/Response
 - ☒ After Final
 - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement; Form PTO-1449
- ☐ Cited References
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts under 37 C.F.R. 1.52 or 1.53
- ☐ Response to Missing Parts/Incomplete Application

- ☐ Drawing(s)
- ☐ Request for Corrected Filing Receipt
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation, Change of Correspondence Address
- ☐ Declaration
- ☐ Statement under 37 CFR 3.73(b)
- ☐ Terminal Disclaimer
- ☐ Request for Refund

- ☐ CD(s), Number of CD(s) _____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group (*Appeal Notice, Brief, Reply Brief*)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Return Receipt Postcard
- ☒ Additional Enclosure(s) (*please identify below*):
Copy of Priority Document
09/451,739

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Individual Name	Julie A. Urvater, Ph.D., Patent Agent	Customer Number 00500
Signature		
Date	October 27, 2003	

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name		
Signature		Date:

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. 427668_1.DOC

